EXHIBIT 8

Dockets.Justia.com

UNITED STATES PATENT AND TRADEMARK OFFICE
DEPARTMENT OF COMMERCE

Intellectual Property Law Summer Institute

July 22, 2006

John Doll
Commissioner for Patents

United States Patent and Trademark Office

Contact Information

John Doll

e-mail: john.doll@uspto.gov

Phone: 571 272 8800 (Receptionist)

571 272 8250 (Direct Line)

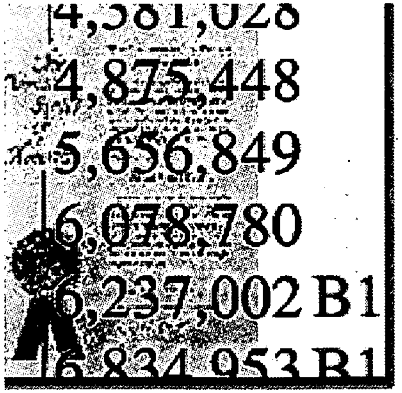
United States Patent and Trademark Office

Agenda

- Claims / Continuations NPR
- Information Disclosure Statement NPR
- Additional Rules Packages under Consideration
- Patent Products
- Efforts to Address Backlog
- Quality Actions and Initiatives

United States Patent and Trademark Office

Claims / Continuations NPR


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Claims NPR

- The USPTO will initially examine only the representative claims, which are:
  - All of the independent claims,
  - The dependent claims designated for initial examination,
  - Dependent claims that are not designated are held in abeyance until the representative claims are in condition for allowance
- Selecting more than 10 representative claims requires submission of an examination support document
  - Or more than 10 independent claims
- Published January 3, 2006; comment period ended May 3, 2006

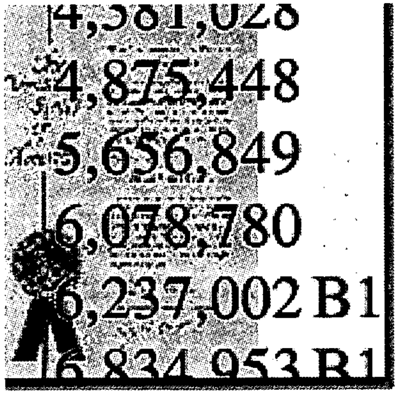
United States Patent and Trademark Office

Continuations NPR

- Limits the number of continuations and RCEs that may be filed by right
- Focuses interaction between applicants and examiners on the initial actions in prosecution
- Allows filing of additional continuations or RCEs with appropriate showing
- Focuses examining resources on new applications
- Published January 3, 2006; comment period ended May 3, 2006

United States Patent and Trademark Office

Information Disclosure Statement NPR


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Information Disclosure Statement NPR

Changes to Information Disclosure Statement Requirements, 71 *Fed. Reg.* 38808 (July 10, 2006)

60 day comment period

Ending September 8th

United States Patent and Trademark Office

Information Disclosure Statement NPR

IDS NPR available on the USPTO web site at:
http://www.uspto.gov/web/offices/com/sol/notices/71fr38808.pdf

To be considered, public comments must be received by September 8, 2006, and may be submitted

- Electronically (AB95.comments@uspto.gov.)
- By mail

  Mail Stop Comments-Patents
  Commissioner for Patents, P.O. Box 1450
  Alexandria, VA 22313 - 1450
- By facsimile (571) 273 - 7707

United States Patent and Trademark Office

Information Disclosure Statement

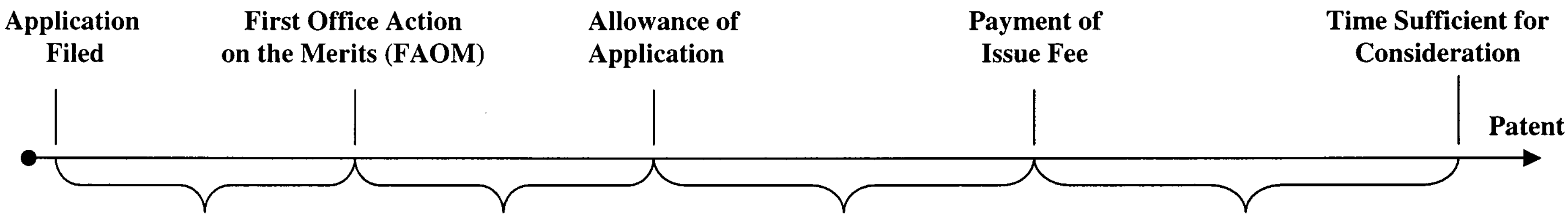
Objectives:

- To provide the examiner with the IDS before the first Office action on the merits.
- To allow the examiner to focus on the most pertinent art.
- To provide the examiner with meaningful information when large documents, foreign language documents, or many documents are submitted.
- To help applicants avoid having to submit an IDS for documents served on them by third parties.
  - Proposed Rule § 1.291

United States Patent and Trademark Office

Information Disclosure Statement

Application Prosecution Timeline and Corresponding IDS Requirements


Application Filed
First Office Action on the Merits (FAOM)
Allowance of Application
Payment of Issue Fee
Time Sufficient for Consideration
Patent

First Period

Up to 20 citations permitted w/o any *explanation* req'd.

- *Explanations* req'd for: each ref. >25 pages, or in non-English language, or for all refs when more than 20

Second Period

- *Explanation*, and
- *Non-cumulative description*

Third Period

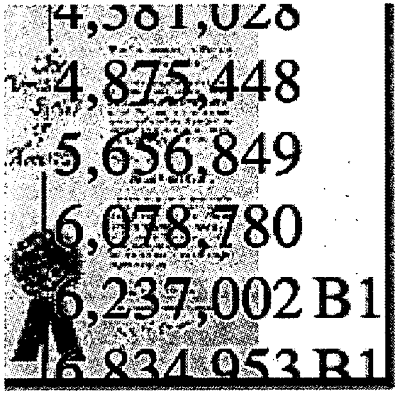
- Timeliness cert., and
- *Patentability Justification* which includes: *Explanation, Non-cumulative description,* and either:
  (A) Patentability reasons for unamended claims; or
  (B)(1) Statement of unpatentable claims,
  (B)(2) Amendment, and
  (B)(3) Patentability reasons for amended claim(s)

Fourth Period

- Timeliness cert.;
- *Patentability Justification* which includes:
  Explanation,
  Non-cumulative description,
  Statement of unpatentable claims,
  Amendment, and
  Patentability reasons for amended claim(s); and
- Petition to w/d from allowance

United States Patent and Trademark Office

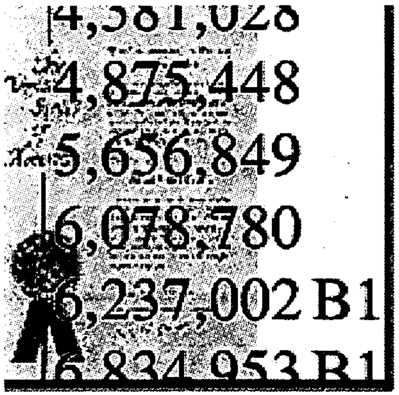
Additional Rules Packages under Consideration


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Additional Rules Packages under Consideration

Markush


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Markush: Example

1. A cell adhesion protein of formula (1),

$$A\text{-}(B)\text{-}(C)\text{-}(D)_n\text{-}E$$

or a pharmaceutically acceptable derivative thereof , wherein . . .

1. A composition comprising molecules for use as tags or tag complements wherein each molecule comprises an oligonucleotide selected from a set of oligonucleotides based on a following group of sequences:

1	4	6	6	1	3
2	4	5	5	2	3
1	8	1	2	3	4
1	7	1	9	8	4
1	1	9	2	6	9
1	2	4	3	9	6
9	8	9	8	10	9
9	1	2	3	8	10
8	8	7	4	3	1
1	1	1	1	1	2
2	1	3	3	2	2
3	1	2	2	3	2
4	1	4	4	4	2
1	2	3	3	1	1
1	3	2	2	1	4
3	3	3	3	3	4
4	3	1	1	4	4
3	4	1	1	3	3
3	6	6	6	3	5
6	6	1	1	6	5
7	6	7	7	7	5
8	7	5	5	8	8
2	1	7	7	1	1
2	3	2	3	1	3
2	6	5	6	1	6
4	8	1	1	3	8
5	3	1	1	6	3
5	6	8	8	6	6
8	3	6	5	7	3
1	2	3	1	4	6
1	5	7	5	4	3
2	1	6	7	3	6
2	6	1	3	3	1
2	7	6	8	3	1
3	4	3	1	2	5
3	5	6	1	2	7
3	6	1	7	2	7
4	6	3	5	1	7
5	4	6	3	8	6

-continued

6	8	2	3	7	1
7	1	7	8	6	3
7	3	4	1	6	8
4	7	7	1	2	4
3	6	5	2	6	3
1	4	1	4	6	1
3	3	1	4	8	1
8	3	3	5	3	8
1	3	6	6	3	7
7	3	8	6	4	7
3	1	3	7	8	6
10	9	5	5	10	10
7	10	10	10	7	9
9	9	7	7	10	9
9	3	10	3	10	3
9	6	3	4	10	6
10	4	10	3	9	4
3	9	3	10	4	9
9	10	5	9	4	8
3	9	4	9	10	7
3	5	9	4	10	8
4	10	5	4	9	3
5	3	3	9	8	10
6	8	6	9	7	10
4	6	10	9	6	4
4	9	8	10	8	3
7	7	9	10	5	3
8	8	9	3	9	10
8	10	2	9	5	9
9	6	2	2	7	10
9	7	5	3	10	6
10	3	6	8	9	2
10	9	3	2	7	3
8	9	10	3	6	2
3	2	5	10	8	9
8	2	3	10	2	9
6	3	9	8	2	10
3	7	3	9	9	10
9	10	1	1	9	4
10	1	9	1	4	1
7	1	10	9	8	1
9	1	10	1	10	6
9	6	9	1	3	10
3	10	8	8	9	1
3	8	1	9	10	3

-continued

9	10	1	3	6	9
1	9	1	10	3	1
1	4	9	6	8	10
3	3	9	6	1	10
5	3	1	6	9	10
6	1	8	10	9	6
5	9	9	4	10	3
2	10	9	1	9	5
10	10	7	2	1	9
10	9	9	1	8	2
1	8	6	8	9	10
1	9	1	3	8	10
9	6	9	10	1	2
1	10	8	9	9	2
1	9	6	7	2	9
4	3	9	3	5	1
5	11	10	14	12	1
7	12	4	13	3	2
5	5	4	4	12	9
2	13	13	11	13	13
10	2	5	4	12	7
11	7	4	11	6	4
12	12	1	9	11	11
12	9	4	14	12	6
12	7	13	2	9	11
9	11	3	4	1	3
10	5	12	11	4	4
4	13	7	12	1	5
9	13	10	11	11	6
10	14	14	10	1	3
2	14	1	10	4	5
10	12	12	7	11	10
9	11	2	12	8	11
2	8	5	2	12	14
1	8	13	3	7	8
9	4	7	5	4	2
13	2	12	7	1	12
11	10	9	7	5	11
8	12	2	2	12	7
5	2	14	3	4	13
1	8	8	1	5	9
14	5	11	10	13	3
14	1	4	13	2	4
4	4	5	11	3	10
10	9	2	3	3	11
11	4	8	14	3	4
5	1	14	8	11	2
14	3	11	6	12	5
13	4	4	1	10	1
6	10	11	6	5	1
5	8	12	5	1	7
4	5	9	6	9	2
13	2	4	4	2	3
11	2	2	5	9	3
8	1	10	12	2	8
12	7	9	11	4	1
12	1	4	14	3	13
11	2	7	10	4	1
3	4	12	11	11	11
3	3	4	2	12	11
1	5	9	4	2	1
6	1	12	2	10	5
10	5	1	12	2	14
2	11	7	9	4	11
7	4	4	5	14	12
12	5	2	1	10	12
5	9	2	11	6	1
12	14	3	6	1	14
5	9	11	10	1	4
2	5	12	14	10	10
4	5	8	4	5	6
10	12	4	6	12	5
4	2	1	13	6	8
9	10	10	14	5	3
6	14	10	11	3	3
2	9	10	12	5	7

-continued

13	3	7	10	5	12
6	4	1	2	5	13
6	1	13	4	14	13
2	12	1	14	1	9
4	11	13	2	6	10
1	10	7	4	5	8
7	2	2	10	13	4
8	2	11	4	6	14
4	8	2	6	2	3
7	1	12	11	2	9
5	6	10	4	13	4
5	10	4	11	9	3
3	11	9	3	2	3
8	15	6	20	17	19
21	10	15	3	7	11
11	7	17	20	14	9
16	6	17	13	21	21
10	15	22	6	17	21
15	7	17	10	22	22
3	20	8	15	20	16
17	21	10	16	6	22
6	21	14	14	14	16
7	17	3	20	10	7
16	19	14	17	7	21
20	16	7	15	22	10
20	10	18	11	22	18
18	7	19	15	7	22
21	18	7	21	16	3
14	13	7	22	17	13
19	7	8	12	10	17
15	3	21	14	9	7
19	6	15	7	14	14
4	17	10	15	20	19
21	6	18	4	20	16
2	19	8	17	6	13
12	12	6	17	4	20
16	21	12	10	19	16
14	14	15	2	7	21
8	16	21	6	22	16
14	17	22	14	17	20
10	21	7	15	21	18
16	13	20	18	21	12
15	7	4	22	14	13
7	19	14	8	15	4
4	5	3	20	7	16
22	18	6	18	13	20
19	6	16	3	13	3
18	6	22	7	20	18
10	17	11	21	8	13
7	10	17	19	10	14

wherein:

(A) each of 1 to 22 is a 4mer selected from the group of 4mers consisting of WWWW, WWWX, WWWY, WWXW, WWXX, WWXY, WWYW, WWYX, WWYY, WXWW, WXWX, WXWY, WXXW, WXXX, WXXY, WXYW, WXYX, WXYY, WYWW, WYWX, WYWY, WYXW, WYXX, WYXY, WYYW, WYYX, WYYY, XWWW, XWWX, XWWY, XWXW, XWXX, XWXY, XWYW, XWYX, XWYY, XXWW, XXWX, XXWY, XXXW, XXXX, XXXY, XXYW, XXYX, XXYY, XYWW, XYWX, XYWY, XYXW, XYXX, XYXY, XYYW, XYYX, XYYY, YWWW, YWWX, YWWY, YWXW, YWXX, YWXY, YWYW, YWYX, YWYY, YXWW, YXWX, YXWY, YXXW, YXXX, YXXY, YXYW, YXYX, YXYY, YYWW, YYWX, YYWY, YYXW, YYXX, YYXY, YYYW, YYYX, and YYYY, and

(B) each of 1 to 22 is selected so as to be different from all of the others of 1 to 22;

(C) each of W, X and Y is a base in which:

(i) (a) W=one of A, T/U, G, and C,

X=one of A, T/U, G, and C,

Y=one of A, T/U, G, and C,

and each of W, X and Y is selected so as to be different from all of the others of W, X and Y,

(b) an unselected said base of (i)(a) can be substituted any number of times for any one of W, X and Y, or

(ii) (a) W=G or C,

X=A or T/U,

Y=A or T/U,

and X≠Y, and

(b) a base not selected in (ii)(a) can be inserted into each sequence at one or more locations, the location of each insertion being the same in all the sequences;

(D) up to three bases can be inserted at any location of any of the sequences or up to three bases can be deleted from any of the sequences;

(E) all of the sequences of a said group of oligonucleotides are read 5' to 3' or are read 3' to 5'; and

wherein each oligonucleotide of a said set has a sequence of at least ten contiguous bases of the sequence on which it is based, provided that:

(F) (I) the quotient of the sum of G and C divided by the sum of A, T/U, G and C for all combined sequences of the set is between about 0.1 and 0.40 and said quotient for each sequence of the set does not vary from the quotient for the combined sequences by more than 0.2; and

(II) for any phantom sequence generated from any pair of first and second sequences of the set L_1 and L_2 in length, respectively, by selection from the first and second sequences of identical bases in identical sequence with each other:

(i) any consecutive sequence of bases in the phantom sequence which is identical to a consecutive sequence of bases in each of the first and second sequences from which it is generated is less than $((\frac{3}{4} \times L)-1)$ bases in length;

(ii) the phantom sequence, if greater than or equal to $(\frac{5}{6} \times L)$ in length, contains at least three insertions/deletions or mismatches when compared to the first and second sequences from which it is generated; and

(iii) the phantom sequence is not greater than or equal to $(\frac{11}{12} \times L)$ in length;

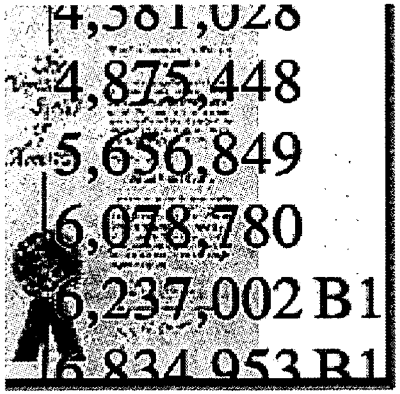
where $L=L_1$, or if $L_1 \neq L_2$, where L is the greater of L_1 and L_2; and

wherein any base present may be substituted by an analogue thereof.

United States Patent and Trademark Office

Additional Rules Packages under Consideration

Examination Support Documents


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Examination Support Documents

- **Four Levels**
  - Patentability report
  - IDS
  - Over 10 representative claims
  - Accelerated examination

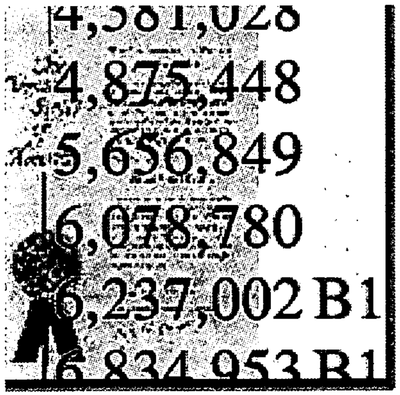
United States Patent and Trademark Office

Examination Support Documents

- **Accelerated Examination**
  - Pre-examination search (US, Foreign, & NPL)
  - IDS complying with 37 CFR 1.98
  - Mapping of all claims to cited references and specification
  - Statement of why claims for examination are deemed patentable in compliance with Rule 111(b & c)

United States Patent and Trademark Office

Patent Products


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Patent Products

- Suite of Patent Products
  - Deferred examination
  - Petty patent
  - Traditional examination
  - Accelerated examination
  - Collaborative examination

United States Patent and Trademark Office

Patent Products: Deferred Examination

Basic Concepts Under Consideration

- Applicant may choose to defer examination for a certain number of years from U.S. filing date, as well as payment of certain fees.
- Applicant may not defer the basic filing fee or any requirements concerning 18-month publication.
- Applicant may activate examination at any time.
- Third party may activate examination after publication.

United States Patent and Trademark Office

Patent Products: Deferred Examination

Expected Benefits

- Non-deferred cases will be examined more quickly.
- The upfront cost of filing will be reduced.
- Delayed payment of certain fees will allow additional time for applicant to consider the commercial viability of inventions before further expenditure of funds.
- The Office can devote its time and resources to applications deemed more pressing by applicants.
- Pendency will be reduced because some applications will not proceed to examination.

United States Patent and Trademark Office

Patent Products: Petty Patent

- Petty Patent
  - Application could undergo less stringent examination based on either Office search or a pre-exam search report.
  - USPTO could use a short form office action.
  - After grant of a "petty patent", applicant still has option for a regular examination under reexam or reissue process.

United States Patent and Trademark Office

Patent Products: Accelerated Examination

- **Accelerated Examination**
  - **12 months to final disposition**
  - **New procedure published on June 26, 2006**
  - **Effective August 25, 2006**
  - **Available on the web at**

http://www.uspto.gov/web/offices/com/sol/notices/71fr36323.pdf
Comments may be sent by e-mail to *MPEPFeedback@uspto.gov*, or by mail to:
Mail Stop Comments—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA, 22313–1450

United States Patent and Trademark Office

Patent Products: Accelerated Examination

- Accelerated Examination
  - "Petitions to Make Special" granted in FY 2005
    - Age and Health: 826
    - Accelerated Examination: 926
    - Quality of Environment, Energy Conservation, Terrorism, Recombinate DNA, Superconductivity, HIV/AIDS, Cancer, Small Entity Biotech: 482
- New procedure replaces all but "age and health"

United States Patent and Trademark Office

Patent Products: Accelerated Examination

- Accelerated Examination
  - Requirements
    - Application must be complete and ready to examine
      - Available for non-reissue utility or design applications.
      - Not available for reexaminations
    - Application must be filed electronically
      - And all follow-on Papers

United States Patent and Trademark Office

Patent Products: Accelerated Examination

- Accelerated Examination
  - Requirements (Continued)
    - 20 or fewer total claims
    - 3 or fewer independent claims
    - No multiple dependent claims
  - Examination Support Document

United States Patent and Trademark Office

Patent Products: Accelerated Examination

Accelerated Examination

- Prior to all rejections, a conference will be held to insure the viability of the rejection.
- An interview will be conducted with applicant before an Office action rejecting the claims is mailed unless an interview is deemed unlikely to overcome the rejection.
- Shortened statutory periods with no extensions of time under 37 CFR 1.136(a).
  - One month (or 30 days) for actions other than a final or allowance.

United States Patent and Trademark Office

Patent Products: Accelerated Examination

Accelerated Examination

- Applicant's Reply
  - Amendments that exceed 3 independent/20 total claim limits or present claims not encompassed by the pre-examination search or an updated accelerated examination support document will be non-responsive.
  - Dependent claims stand or fall together with the independent claims in any appeal.

United States Patent and Trademark Office

Patent Products: Accelerated Examination

- **Accelerated Examination**
  - Applicant's Reply (Continued)
    - An updated Examination Support Document is required for any amended or newly added claim not covered by the original document.
    - Any reply must be filed via EFS-Web in order for the examination to be completed within 12 months.

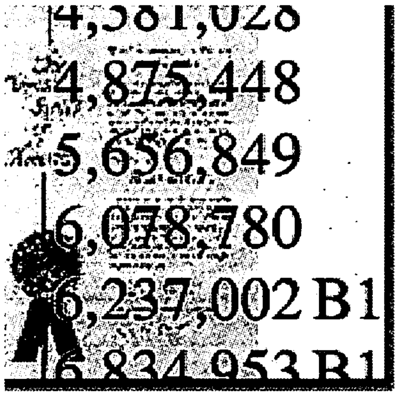
United States Patent and Trademark Office

Patent Products: Collaborative Examination

- **Collaborative Examination**
  - Application examined by a team of expert examiners / attorneys
  - Patentability Report
  - Peer Review
  - Attorney / Examiner Interviews
  - A large cost recovery fee

United States Patent and Trademark Office

Hiring and Retention


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Hiring and Retention

- Hiring 1,000 or more new examiners yearly for the next 5 years
  - Current goal of 1,200 new examiners in FY 2006
- New Training Academy
  - 8 months of training versus old model

United States Patent and Trademark Office

Hiring and Retention

- Enhanced Recruitment and Retention
  - Recruitment Bonuses
  - Retention Bonuses
  - OPM Applicant Aptitude Testing

Hires and Attritions

	1600	1700	2100	2600	2800	3600	3700	Corps	Design
FY 04 Hires	75	35	115	116	31	26	45	443	15
FY 04 Attritions	30	26	58	82	58	43	39	336	4
FY 05 BOY Examiner Staff	417	440	563	658	742	422	439	3681	72
FY 05 Hiring	101	58	225	169	184	91	131	959	19
FY 05 Attrits	42	39	93	92	54	55	50	425	10
FY 06 Hiring Goal	95	70	755			130	150	1200	20
FY 06 hires (7/10/06)	83	43	418			93	101	738	15
FY05 Hires as a Percent of Examiner Staffing in the TC	24%	13%	40%	26%	25%	22%	30%	26%	26%

United States Patent and Trademark Office

Hiring and Retention

- Satellite / Regional Office(s)
  - Increased pool of potential examiners
  - Retention / Morale
  - Employer of Choice

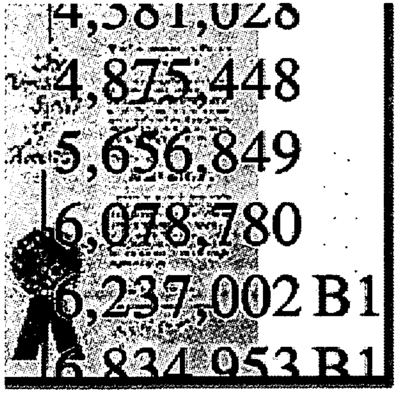
United States Patent and Trademark Office

Hiring and Retention

- Partner with Colleges/Universities
  - Certification Programs
  - Degree Programs
  - Co-op Programs

United States Patent and Trademark Office

Quality Actions and Initiatives


4,875,448
5,656,849
6,078,780
6,237,002 B1

United States Patent and Trademark Office

Quality Actions and Initiatives

- **Allowance error rate**
  - FY 2006 Goal is 4%
  - Currently 3.7%
  - FY 2005: 4.6%
  - FY 2004: 5.3%
- **In-process reviews**
  - Goal is 86% compliance
  - Currently at 90.0%
  - FY 2005: 86.2%
  - FY 2004: 82%

United States Patent and Trademark Office

Quality Actions and Initiatives

- Pre Appeal Brief Conferences
- Appeal Conferences

United States Patent and Trademark Office

Quality Actions and Initiatives

- Second Pair of Eyes second half of last year in ALL allowed applications
- Second Pair of Eyes in selected technology areas this year

United States Patent and Trademark Office

Quality Actions and Initiatives

- Certification Exam before promotion to GS-13
- Primary Examiner Re-certification Program
- Specialized Mandatory Quality Training in certain Technology Centers

United States Patent and Trademark Office

Quality Actions and Initiatives

- Peer Review Pilot
  - Public sector volunteer experts will review voluntarily published applications.
  - The expert will then provide prior art with discussion to a public sector community of experts.
  - Community experts and a moderator will filter the prior art and submit the 10 best references within 2 months of publication under existing rule 37 CFR 1.99.

United States Patent and Trademark Office

Quality Actions and Initiatives

- Number of Researched OPQA Reviews
- Getting the best art in the application
  - Open Source Software Databases

United States Patent and Trademark Office

Quality Actions and Initiatives

- Targeted Reviews in Problem Areas
  - Means to validate the accuracy and magnitude of examination process complaints
  - Examples of such processes or functions at the Corps level are:
    - Restrictions
    - Final Rejections
    - After-Final Practice

United States Patent and Trademark Office

Quality Actions and Initiatives

- External Validation of OPQA Data
  - Conflict of Interest Issues
    - Quasi-government corporation
    - Attorneys on sabbatical
- Quality Award for Examiners

United States Patent and Trademark Office

Contact Information

John Doll

e-mail: john.doll@uspto.gov

Phone: 571 272 8800 (Receptionist)

571 272 8250 (Direct Line)